UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JUDITH GODINEZ, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, v. ALERE INC., NAMAL NAWANA, JAMES F. HINRICHS, and CARLA R. FLAKNE, Defendants.	Civil Action No. 1:16-cv-10766-PBS **MOTION FOR LEAVE TO FILE EXCESS PAGES GRANTED ON JANUARY 3, 2017.**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE SUPPLEMENTAL AND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

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February 6, 2017

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES AND RULES

OTHER AUTHORITIES

Defendants Alere Inc. ("Alere" or the "Company"), Namal Nawana, James F. Hinrichs, and Carla R. Flakne (the "Individual Defendants" or, together with Alere, "Defendants") respectfully submit this memorandum of law in support of their motion to dismiss the Supplemental and Amended Consolidated Class Action Complaint (the "Complaint") under Fed. R. Civ. P. 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act of 1995 (the "PSLRA").

PRELIMINARY STATEMENT

The Complaint, for all its length, fails to state a claim for multiple reasons.

First, Plaintiffs allege securities fraud based on Alere's disclosure that it had incorrectly applied accounting rules for revenue recognition to a limited number of transactions, principally involving its subsidiaries doing business in China and Africa. But, it is undisputed that the errors all involved *real revenue* that was recognized prematurely and that the timing adjustments at issue involve 0.5% or less of net revenue and gross profit. These immaterial revisions undermine any inference of scienter and lend support to the more plausible inference to be drawn from the facts alleged in the Complaint: These were nothing more than good-faith accounting errors by the personnel of foreign subsidiaries. (*See infra* pages 11–20.)

Second, Plaintiffs claim that Alere's announcement in July 2016 that it would recall its INRatio diagnostic products means that the Company fraudulently misrepresented its financial statements two years earlier by failing to establish a loss reserve in 2014. But this is fraud by hindsight. Plaintiffs' own allegations and the documents they cite show that Alere made timely and accurate disclosures regarding the issues associated with its INRatio products and told the market that it was investigating the problems and working on an improvement. Alere continued to significantly invest in research and development to fix the issues and satisfy all regulatory requirements. These facts do not give rise to a strong inference of scienter, and

Plaintiffs offer no basis to infer that Defendants knew that Alere's efforts would ultimately fall short two years later. Indeed, if Defendants always knew that their efforts to improve the product would be futile, it would have been irrational to devote additional resources to this project. (*See infra* pages 22–29.)

Third, the Complaint alleges that Alere has engaged in billing fraud in its toxicology business and violated the Foreign Corrupt Practices Act ("FCPA"). But, for these claims, the Complaint relies almost entirely on the fact that Alere has recently received investigatory subpoenas on these subjects. Plaintiffs do not allege that any regulator has made findings of any wrongdoing or that any enforcement action has ever been filed. (*See infra* pages 29–33.)

Fourth, Plaintiffs allege that Alere had a duty to disclose that (i) according to the government, its subsidiary Arriva Medical, LLC ("Arriva") purportedly submitted 211 claims over a five-year period to the Center for Medicare and Medicaid Services ("CMS") on behalf of deceased patients, and (ii) in August 2015, CMS restricted Arriva's access to the HIPAA Eligibility Tracking System ("HETS"), thereby allegedly adversely affecting Arriva's ability to submit valid claims. The Complaint is devoid of any allegations that, if true, would establish that Defendants knew, or were reckless in not knowing, of these alleged improper claims, and Plaintiffs acknowledge that Alere only received notice from CMS in mid-October 2016, shortly before Alere disclosed it. These claims represent less than 0.003% of the 5.7 million claims Arriva submitted in this period and thus the more compelling inference is that senior management had no knowledge of these errors. (*See infra* pages 33–36.)

Fifth, Plaintiffs heavily rely on various unproven allegations made by Abbott Laboratories ("Abbott"), which made an unsolicited offer to acquire Alere and remains contractually obligated to complete that transaction. The Complaint merely echoes statements

Abbott has made in an effort to gain leverage to scuttle the deal it once ardently sought, and which it subsequently began to spurn after successfully entering into another deal with St. Jude Medical, Inc. ("St. Jude"). The Complaint does not even come close to alleging why these legal skirmishes amount to securities fraud. Plaintiffs do not allege that any court has upheld Abbott's opportunistic assertions, and the deal currently is still moving forward. (*See infra* pages 36–38.)

However, the Complaint suffers from a more fundamental flaw as well, which infects every claim asserted: There are simply no allegations from which a strong inference could be drawn that any of the Individual Defendants participated in, approved of, or knew or were reckless in not knowing about any of the complained of conduct. No confidential witness ascribes such knowledge or involvement to the Defendants. And the alleged actions of Messrs. Nawana and Hinrichs, Alere's Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), respectively, are completely inconsistent with the notion that they knew that Alere's common stock price was artificially inflated: Mr. Nawana's shareholdings increased by over 113,000 shares during the alleged class period (May 28, 2015 to December 7, 2016, inclusive); and, Mr. Hinrichs, who had no shares at the outset of the class period, acquired over 46,000 shares, including by paying about $1.4 million in cash out of his own pocket to purchase shares when the stock price was trading near or above $40 per share.

For all these reasons, as discussed in greater detail below, Defendants respectfully submit that the Complaint should be dismissed, with prejudice, in its entirety.

STATEMENT OF FACTS[1]

The Business of Alere Inc.

Alere is an international company that provides diagnostic tests and services, with a focus on infectious disease, cardiometabolic disease, and toxicology.[2] The Company's principal executive offices are in Waltham, Massachusetts,[3] but it operates in numerous foreign countries through more than 50 subsidiaries and employs approximately 9,200 people worldwide.[4] Its products are sold globally through a distribution network in 32 countries, its own sales force, and third-party distributors.[5] Alere's total net revenue was $2.46 billion in 2015 and $2.58 billion in 2014, with approximately 74% from the United States and Europe.[6]

The Individual Defendants

Individual Defendants Namal Nawana and James F. Hinrichs are Alere's current CEO and CFO, respectively. Mr. Nawana joined Alere (initially as its Chief Operating Officer) in December 2012, and Mr. Hinrichs joined Alere on April 6, 2015. Individual Defendant Carla R. Flakne was Alere's Chief Accounting Officer from August 2013 until her retirement on March 31, 2016.[7] During the alleged class period, Messrs. Nawana and Hinrichs both substantially

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1 On a motion to dismiss pursuant to Rule 12(b)(6), a "court may consider documents attached to or expressly incorporated into the Complaint, as well as documents the authenticity of which are not disputed by the parties, official public records, documents central to the plaintiffs' claim, and documents sufficiently referred to in the complaint[.]" *Aronson* v. *Advanced Cell Tech., Inc.*, 902 F. Supp. 2d 106, 112 (D. Mass. 2012); *see also Brennan* v. *Zafgen, Inc.*, -- F. Supp.3d --, 2016 WL 4203413, at *3 (D. Mass. Aug. 9, 2016). Citations in the form of "¶ __" refer to paragraphs of the Complaint. Citations in the form of "Ex. __" refer to exhibits to the Declaration of Richard A. Rosen, dated February 6, 2017. As explained in the Declaration, all exhibits are either incorporated by reference or sufficiently referred to in the Complaint, central to the Plaintiffs' claims, or publicly available SEC filings.

2 ¶ 1.

3 ¶ 14.

4 Ex. 13, at 13, 40–42.

5 Ex. 13, at 7–8.

6 Ex. 13, at 8. Approximately 18% and 21% of Alere's net revenue was generated from Europe in 2014 and 2015, respectively. *Id.*

7 Ex. 7, at 2.

increased their holdings of Alere common stock. Specifically, Mr. Hinrichs increased his shares by 46,666. He purchased 30,000 of these shares on the open market, paying about $1.4 million of his own money.[8] Mr. Nawana's vested common stock holdings increased from 5,903 to 119,042 shares. Mr. Nawana has never sold any Alere shares during his tenure as CEO, except to pay the tax liabilities associated with the vesting of his options and restricted stock units.[9]

The Revisions to Alere's Financial Statements

In late February 2016, Alere's senior management learned of several issues in Africa and China that could impact revenue reported in Alere's 2015 financial statements.[10] Alere promptly disclosed, on February 26, 2016, that the filing of its Annual Report on Form 10-K for 2015 ("2015 Form 10-K") would be delayed while it analyzed revenue recognition issues in those regions.[11] Alere's Audit Committee, with the advice and assistance of independent counsel, directed an extensive analysis that included searching millions of emails, reviewing hundreds of customer contracts, and testing thousands of transactions to determine whether revenue for these transactions had been recognized in accordance with Generally Accepted Accounting Principles ("GAAP").

On July 14, 2016, Alere announced the preliminary results of its review: It had erred by prematurely recognizing immaterial amounts of revenue from 2013 to the third quarter of 2015. As the Company explained—and Plaintiffs do not dispute—the errors involved genuine transactions and real revenues that had been recorded in the wrong quarter due to the misapplication of GAAP. The transactions fell into three categories:

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8 Ex. 21, at 8, 10, 13. Since joining Alere, Mr. Hinrichs has also been awarded restricted stock units and employee stock options, none of which has been sold upon vesting.

9 Ex. 21, at 7, 9, 11–12, 14.

10 Ex. 13, at 2.

11 ¶ 74.

(i) transactions, principally in Africa, in which Alere recognized revenue when the product shipped to the distributor, but it contractually retained title until the distributor paid for the products in full or the distributor was not obligated to pay until the products were sold through to the customer;

(ii) "bill and hold" transactions, principally in China, which did not meet the GAAP criteria for revenue recognition; and

(iii) other transactions for which Alere recognized revenue before all the contractual criteria for title and risk of loss passing to the customer were fully satisfied.[12]

Alere corrected the errors in its 2015 Form 10-K (filed on August 8, 2016) by revising its consolidated financial information for the fiscal years 2013 and 2014, the interim periods in 2014, and the first three quarters of 2015.[13]

These adjustments reduced Alere's annual net revenue in 2013 and 2014 by $7.7 million and $13.4 million, respectively. Alere has, since then, recognized $12 million of that same revenue in the fourth quarter of 2015 and $5 million, $3 million, and $1 million, respectively, in each of the first three quarters of 2016.[14] Thus, as Alere's 10-Q for the third quarter of 2016 confirms, "none [of the revenue] remained deferred at September 30, 2016."[15]

Alere concluded, and its independent auditors PricewaterhouseCoopers LLP ("PwC") agreed, that the revisions were not "material, individually or in the aggregate, to any of [Alere's] previously issued quarterly and annual financial statements" and a restatement was therefore not necessary.[16] Indeed, Alere's key financial metrics were not materially impacted:

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[12] Ex. 12, at 4.

[13] Specifically, Alere adjusted the quarter in which it recognized revenues for these transactions to "the period in which physical delivery occurred as defined by the contractual relationship; or title and risk of loss had transferred to the buyer; or the buyer had the contractual obligation to pay the amounts invoiced." Ex. 13, at 2–3.

[14] Ex. 15, at 4 (stating that approximately $9 million and $4 million of revenue remained deferred as of December 31, 2015 and March 31, 2016, respectively); Ex. 16, at 4 (stating $1 million of revenue remained deferred as of June 30, 2016); Ex. 18, at 6 (stating no revenue remained deferred as of September 30, 2016).

[15] Ex. 18, at 6.

[16] Ex. 13, at 25, 32–33.

- **Net revenue** was adjusted by **0.5% or less** in 2013, 2014, and the first 9 months of 2015.[17]
- **Gross profit** was adjusted by **0.5% or less** in 2013, 2014, and the first 9 months of 2015.[18]

The revisions did not impact net cash flows, including those from operating activities.[19]

The Voluntary Recall of Alere's INRatio Products

On July 11, 2016, Alere announced that it was voluntarily recalling its INRatio products.[20] Previously, in May 2014, Alere had voluntarily recalled one of its INRatio test strips due to a concern that the product may report inaccurate results and transitioned users to another INRatio product.[21] Later, in December 2014, Alere issued a voluntary correction to advise users of its INRatio products that patients suffering from certain specified conditions (such as advanced stage cancer, bleeding, chronic or acute inflammatory conditions, or severe infection, among others) should not use them.[22] In both instances, Alere disclosed that it had proactively reported its concerns about the INRatio products to the Food and Drug Administration ("FDA") and was "conducting a thorough investigation into these events."[23] Alere also disclosed in December 2014 that it was working on an improvement for the devices.[24] On March 5, 2015, Alere stated, "While it is too early to understand the full impact of the voluntary urgent medical device correction, . . . [w]e plan to continue our improvements to quality and regulatory compliance during 2015 and beyond."[25]

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17 In the first 9 months of 2015, net revenue was adjusted by 0.03%. *See* Ex. 13, at 25–27, 37–38.

18 In the first 9 months of 2015, gross profit was adjusted by 0.01%. *See* Ex. 13, at 25–27, 37–38.

19 Ex. 13, at 3.

20 The INRatio is a "hand-held blood coagulation monitoring system for use by patients and healthcare professions in the management of warfarin, a commonly prescribed medication used to prevent blood clots." *See* ¶ 45.

21 Ex. 3, at 1.

22 Ex. 4, at 1.

23 Ex. 4, at 2; Ex. 3, at 2.

24 Ex. 4, at 2.

25 Ex. 5, at 15.

Alere continued to invest in additional research and development for INRatio and submitted enhancements to the FDA at the end of 2015.[26] Ultimately, however, the FDA advised Alere that it was not satisfied that Alere's studies demonstrated the enhancements' effectiveness and advised Alere to submit a proposal for voluntary removal. Shortly thereafter, in July 2016, Alere voluntarily decided to recall the INRatio products from the market.[27] In 2015, sales from INRatio products had generated approximately $20.4 million in revenue, or around 0.8% of Alere's total net revenue.[28] In connection with the voluntary recall, Alere recorded a charge of approximately $38 million in 2015, most of which was attributable to non-cash charges for impairments to INRatio inventory and production equipment.[29]

Disclosures of Preliminary Regulatory Investigations

As Alere promptly disclosed, the Company is currently responding to two subpoenas in unrelated preliminary investigations, with which it is cooperating. The first is a DOJ subpoena received in July 2016 that seeks Medicare, Medicaid, and Tricare billing records from Alere's Austin, Texas laboratory. These records accounted for "significantly less than 1% of Alere's total revenues" in the first 9 months of 2015.[30] The other is a DOJ grand jury subpoena regarding FCPA compliance in Africa, Asia, and Latin America.[31] Plaintiffs do not allege that either of these investigations has resulted in the commencement of an enforcement action, any factual findings, or the issuance of any fines or penalties against Alere or its personnel.

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[26] Ex. 13, at 12–13; Ex. 11, at 5.

[27] Ex. 13, at 12–13.

[28] Ex. 13, at 15 (noting 2015 INRatio revenue), 34 (reflecting Alere's net revenue of $2.5 billion for the fiscal year 2015).

[29] Ex. 13, at 23 (disclosing that about $18 million is attributable to inventory impairment, about $3 million production equipment impairment, and about $16 million to estimated costs of implementing the recall).

[30] Ex. 10, at 1.

[31] ¶ 61.

Arriva Medical LLC's Eligibility to Bill Medicare

Alere's subsidiary Arriva, which is headquartered in Coral Springs, Florida, is a mail order supplier of diabetic testing products that are primarily covered by Medicare, Medicaid, and other third-party payers.[32] On October 12, 2016, without any prior notice, Arriva received a letter from CMS notifying it that its eligibility to submit claims to Medicare would be revoked effective November 4, 2016. The purported basis for the revocation was that Arriva had allegedly submitted claims for reimbursement on behalf of 211 deceased patients over a five-year period.[33] CMS does ***not*** suggest in its letter to Arriva that (i) claims were intentionally submitted on behalf of deceased beneficiaries, (ii) either Alere or Arriva knew of such improper submissions, (iii) the claims caused any financial harm to the Medicare program, or (iv) there is a public health risk from these improper submissions. Nor does the Complaint allege that the CMS letter contained any of these suggestions.[34]

Alere promptly disclosed the CMS charges and the revocation of Arriva's eligibility to bill Medicare after receiving the notification letter from CMS.[35] The 211 claims constitute less than 0.003% of the 5.7 million claims Arriva submitted in this period for its services to over 970,000 Medicare beneficiaries (about 138,000 of whom passed away during this period).[36] Arriva regularly monitors and audits a sample of its patients' orders and submitted claims using a third-party, independent vendor, and the Complaint does not allege that the independent monitor

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[32] ¶ 192; Ex. 19, at 1.

[33] ¶ 133.

[34] *See* ¶¶ 133–139; 192–205.

[35] ¶ 133; *see also* Ex. 18, at 5.

[36] Ex. 19, at 1; Ex. 18, at 5. The Complaint selectively alleges information from the Fact Sheet that Arriva disclosed on November 14, 2016 regarding CMS's revocation of its eligibility to bill Medicare, but disregards other crucial facts. *See, e.g.*, ¶ 205.

ever flagged any invalid claims.[37] Alere is vigorously appealing CMS's decision with the goal of reactivating Arriva's eligibility to submit claims to Medicare and receiving reimbursement for all claims submitted after November 4.[38]

The Pending Merger with Abbott Laboratories

On December 10, 2015, Abbott made an unsolicited overture to acquire Alere.[39] During the due diligence process, Alere provided extensive materials to Abbott. After completing its due diligence, Abbott entered into an agreement to acquire Alere on January 30, 2016 (the "Merger Agreement").[40] On April 19, 2016, Abbott sought to terminate the Merger Agreement citing concerns about the delay in filing Alere's 2015 Form 10-K and the government investigations. After Alere rejected the offer to terminate, Abbott affirmed on April 21 that it would abide by its obligations under the Merger Agreement.[41] A week later, on April 28, the apparent reason for Abbott's case of buyer's remorse was revealed when Abbott announced that it also had agreed to acquire St. Jude.[42]

Abbott's continued efforts to scuttle its agreement with Alere has resulted in ongoing litigation before the Delaware Court of Chancery, including: (i) a lawsuit filed by Alere on August 25, 2016 seeking to compel Abbott to fulfill its obligations to promptly obtain all required antitrust approvals;[43] (ii) a breach of contract lawsuit filed by Abbott on November 3,

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37 Ex. 19, at 1.

38 Ex. 18, at 5.

39 Ex. 17, at 15. Plaintiffs allege in a conclusory fashion that "Alere executives decided to sell Alere" by mid-2014, *see* ¶ 21; however, they cite no facts to support their contention. Alere had not put itself up for sale. Rather, like most public companies, it was continuously evaluating its strategic options and considering how it might maximize shareholder value—a fact that is reflected in the Proxy Statement. *See* Ex. 2, at 5; Ex. 17, at 14.

40 Ex. 17, at 15–18, 22.

41 Ex. 17, at 23.

42 Ex. 17, at 23.

43 ¶ 124; *see also* Complaint, *Alere Inc.* v. *Abbott Labs*., C.A. No. 12691-VCG (Del. Ch. Aug. 25, 2016).

2016 alleging that Alere had failed to provide Abbott access to certain financial information;[44] and (iii) a lawsuit filed by Abbott on December 7, 2016 seeking to terminate the deal with Alere on the ground of a material adverse event ("MAE") under the Merger Agreement.[45] Plaintiffs in this action quote liberally from Abbott's various court filings, including Abbott's allegations regarding Alere's financial statements, the INRatio recall, pending regulatory investigations, and CMS's revocation of Arriva's Medicare eligibility.[46]

ARGUMENT

I. PLAINTIFFS FAIL TO PLEAD SECURITIES FRAUD REGARDING ALERE'S REVISED FINANCIAL STATEMENTS.

A. Plaintiffs Fail to Plead Particularized Allegations Raising a Strong Inference of Scienter Regarding Revenue Recognition.

Plaintiffs' principal allegation in this action is that Defendants knew, or were reckless in not knowing, that Alere's 2013 and 2014 financial statements had incorrectly recognized revenue for certain transactions. For this claim[47] to survive a motion to dismiss, the PSLRA's heightened pleading standards require Plaintiffs to state "with particularity facts giving rise to a 'strong inference' that defendants acted with a conscious intent to deceive or defraud investors . . . or acted with a high degree of recklessness." *Fire & Police Pension Ass'n of Colorado* v. *Abiomed, Inc.*, 778 F.3d 228, 240 (1st Cir. 2015) (citations and internal quotation marks omitted); 15 U.S.C. § 78u-4(b)(2). Recklessness is an "extreme departure from the standards of ordinary care . . . which presents a danger of misleading buyers or sellers that is either known to

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[44] ¶¶ 3, 131–132.

[45] ¶¶ 3, 140. The matters in Delaware have been consolidated and are proceeding on an expedited schedule, with an anticipated trial date of April 21, 2017. Alere's position is that Abbott's allegations are without merit.

[46] *See, e.g.*, ¶¶ 126, 127, 170–171, 241–242.

[47] To state a claim under Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a *et. seq.* (the "Exchange Act") and Rule 10b-5 thereunder, 17 C.F.R. § 240.10b-5, a plaintiff must allege "(1) a material misrepresentation or omission; (2) scienter, or a wrongful state of mind; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation." *ACA Fin. Guar. Corp.* v. *Advest, Inc.*, 512 F.3d 46, 58 (1st Cir. 2008) (citing *Dura Pharm., Inc.* v. *Broudo*, 544 U.S. 336, 341–42 (2005)).

the defendant or is so obvious the actor must have been aware of it." *City of Dearborn Heights Act 345 Police & Fire Ret. Sys.* v. *Waters Corp.,* 632 F.3d 751, 757 (1st Cir. 2011). "[A]llegations of merely unreasonable conduct do not sufficiently plead scienter." *Local No. 8 IBEW Ret. Plan* v. *Vertex Pharms., Inc.*, 838 F.3d 76, 80, n.6 (1st Cir. Oct. 3, 2016).

The Complaint, however, fails to raise any such strong inference of scienter because (i) mere GAAP violations, especially where complex judgments are necessary to apply the rules to the particular facts (as in this case) are insufficient, (ii) the amounts of the prematurely recognized revenue were immaterial, and (iii) the allegations do not support an inference that any Defendant knew about the errors and no confidential witness attributes such knowledge to any Defendant.

First, Plaintiffs allege that the fact that Alere had to revise its financial statements because of a misapplication of GAAP rules and its own revenue recognition policy (which is consistent with GAAP rules) supports a strong inference of scienter.[48] However, it is settled law that revisions to financial results or the identification of "GAAP violations or accounting irregularities, standing alone, are insufficient to state a securities fraud claim." *Smith* v. *First Marblehead Corp.*, 55 F. Supp. 3d 223, 231 (D. Mass. 2014) (quoting *Day* v. *Staples, Inc.*, 555 F.3d 42, 45 (1st Cir. 2009)); *see also In re Turquoise Hill Res. Ltd. Sec. Litig.*, No. 13 Civ. 8846, 2014 WL 7176187, at *7 (S.D.N.Y. Dec. 16, 2014) ("[A] restatement is simply a correction, after the fact, of an accounting or other error in financial results. The fact of an error, even a large error, does not suggest knowledge or intent to misstate when the financial results were originally published[.]").[49]

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[48] *See, e.g.*, ¶¶ 145–171, 235.

[49] *Accord In re Segue Software, Inc. Sec. Litig.*, 106 F. Supp. 2d 161, 169 (D. Mass. 2000) ("[A] restatement of earnings, without more, does not support a strong inference of fraud, or for that matter, a weak one."); *In re BISYS Sec. Litig.*, 397 F. Supp. 2d 430, 448 (S.D.N.Y. 2005) (explaining that plaintiff's allegations that financial

This principle is particularly germane here, where there were no fictitious sales or phantom revenue, but rather *real revenue* that was recognized in the wrong quarters for transactions occurring principally in Africa and China.[50] For most of the transactions, the errors occurred because Alere recognized revenue when it delivered the products, which is typically when revenue is earned.[51] Recognizing revenue at the time of delivery is indeed consistent with Staff Accounting Bulletin ("SAB") Topic No. 13 (the SEC's guidance on revenue recognition rules),[52] SAB 104 (subsequent guidance revising or rescinding parts of Topic No. 13),[53] and Alere's own revenue recognition policy—all of which are cited repeatedly in the Complaint.[54]

As Alere's 2015 Form 10-K explains in detail (and without any challenge from Plaintiffs), under the terms of certain sales contracts in Africa, (i) Alere had "retained title in the products until the distributor paid for the products in full," (ii) "the distributor was not obligated to pay [Alere] until the products were sold through to the end-user," or (iii) the "title and risk of loss [had not] pass[ed] to the customer."[55] To determine when to recognize revenue, Alere had to apply the GAAP revenue recognition rules to the idiosyncratic terms of each sales contract separately—a necessarily fact-sensitive and complex endeavor. *See Casula* v. *athenahealth, Inc.*,

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improprieties violated the company's own internal accounting policies do not contribute to an inference of scienter because they "merely establish that the reports were false," not that "the Individual Defendants issued those reports with the requisite fraudulent intent"); *In re Cirrus Logic Sec. Litig.*, 946 F. Supp. 1446, 1458 (N.D. Cal. 1996) ("[T]here can be no claim of fraud based merely on a company's deviation from its own undisclosed internal accounting policies." (citations omitted)).

50 *Cf. In re Lernout & Hauspie Sec. Litig.*, 208 F. Supp. 2d 74, 76 (D. Mass. 2002).

51 Delivery "is often the time when revenue is considered earned, because the risks and rewards of ownership generally rest with the holder of the products and, therefore, pass to the buyer at delivery." Scott A. Taub, *Revenue Recognition Guide* 5009 (2016); *see also In re Stellent, Inc. Sec. Litig.*, 326 F. Supp. 2d 970, 981 (D. Minn. 2004) ("Under GAAP, revenues should 'not [be] recognized until *earned*,' which usually occurs once 'the product or merchandise is delivered.'" (quoting Financial Accounting Standards Board ("FASB") Statements of Concepts No. 5, ¶ 83(b)) (emphasis and alterations in original)).

52 SAB No. 13, 11 SEC Docket 1403 (Jan. 4, 1977).

53 SAB No. 104, 68 Fed. Reg. 74436 (Dec. 17, 2003).

54 *See* ¶¶ 153–156.

55 Ex. 13, at 2.

No. 10-10477-GAO, 2011 WL 4566115, at *6 (D. Mass. Sept. 30, 2011) (dismissing Section 10(b) claim premised on a restatement due to a GAAP violation because the guidance in SAB 104 is "not only nuanced but subject to evaluation depending on a 'case-by-case' consideration of 'specific facts and circumstances'").[56]

The other errors involved bill-and-hold transactions, which are permissible under GAAP, but require the application of complex and highly fact sensitive rules to assess when revenue may be recognized. *See* Scott A. Taub, *Revenue Recognition Guide* 5022 (2016).[57] As the numerous SAB 104 criteria quoted by Plaintiffs make clear,[58] evaluating bill-and-hold transactions "require[s] significant judgment to determine whether the transaction represents a sale."[59] In fact, in "some circumstances, a transaction may meet all the factors listed [in SAB 104] but not meet the requirements for revenue recognition."[60]

Under the circumstances, the misapplication of the GAAP rules for both the bill-and-hold transactions and sales contracts containing idiosyncratic terms fails to raise an inference of scienter. As a leading revenue recognition treatise states, "Getting revenue recognition right

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[56] *See also In re Turquoise Hill*, 2014 WL 7176187, at *6 ("[T]he Complaint does not support the conclusion that application of the relevant revenue recognition accounting principles was necessarily obvious or straightforward."); *N. Collier Fire Control & Rescue Dist. Firefighter Pension Plan & Plymouth Cnty. Ret. Ass'n* v. *MDC Partners, Inc*., No. 15 CIV. 6034 (RJS), 2016 WL 5794774, at *10 (S.D.N.Y. Sept. 30, 2016) (dismissing securities fraud claims relating to purported overstatements of goodwill on grounds that GAAP "tolerate[s] a range of reasonable treatments, leaving the choice among alternatives to management" (citation and internal quotation marks omitted)).

[57] *See also* Sec. Exch. Comm'n, *Report Pursuant to Section 704 of the Sarbanes-Oxley Act of 2002*, 9 n.21 (Jan. 24, 2003), *available at* https://www.sec.gov/news/studies/sox704report.pdf (last visited Feb. 5, 2017) ("[Bill-and-hold] transactions may be recognized legitimately under GAAP when special criteria are met, including being done pursuant to the buyer's request.").

[58] ¶¶ 153–155.

[59] Ernst & Young Global Limited ("E&Y") made this observation in a comment letter to members of the FASB and the International Accounting Standards Board ("IASB") regarding their draft of a new principles-based standard aimed at clarifying the principles for recognizing revenue and developing a common revenue standard for U.S. GAAP and IFRS. *See* Letter from E&Y to FASB and IASB members 5 (Nov. 27, 2012), *available at* http://www.ey.com/publication/vwluassetsdld/commentletter_bb2441_igfored2_27november2012/$file/commentletter_bb2441_igfored2_27november2012.pdf?OpenElement (last visited Feb. 5, 2017).

[60] ¶ 154.

requires navigating complex and sometimes inconsistent accounting literature and making difficult judgments."[61] Given the fact-sensitive GAAP rules and complex judgments necessary for the transactions involved here, the inference of scienter is not as "cogent and at least as compelling as [the] opposing inference" that the revenue recognition errors were inadvertent. *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314, 324 (2007).[62]

Second, the impact of the revisions to Alere's key financial metrics was immaterial, so the more reasonable inference is that the errors were unintentional. *See In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d 744, 750 (1st Cir. 2016) ("'[T]he materiality and scienter inquiries are linked' . . . because the marginal materiality of an omitted fact 'tends to undercut the argument that defendants acted with the requisite intent in not disclosing' it." (internal citations omitted)). As discussed above, the revisions had a 0.5% or less impact on Alere's gross profits and net revenues in 2013, 2014, and the first 9 months of 2015. Courts have held that even percentage changes that are much larger than these are insufficient as a matter of law to raise a strong inference of scienter. *See Greebel* v. *FTP Software, Inc.*, 194 F.3d 185, 206 (1st Cir. 1999) (holding that improperly recognizing approximately 4.2% of revenue did not support a strong inference of scienter); *In re Segue Software, Inc. Sec. Litig.*, 106 F. Supp. 2d 161, 171 (D. Mass. 2000) (holding that an overstatement of 2.6% in revenues was "insignificant").[63] It is not

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[61] Taub, *Revenue Recognition Guide*, at v.

[62] There are circumstances in which GAAP violations could support an inference of scienter, none of which are present in this case. For instance, in *In re Raytheon Sec. Litig.*, 157 F. Supp. 2d 131 (D. Mass. 2001) (Saris, C.J.), this Court found that the plaintiff had adequately pleaded scienter in connection with a misapplication of GAAP where (i) the magnitude of the accounting error was significant and (ii) contemporaneous internal documents recognized losses that were not disclosed in the company's public filings. *Id. at* 148–49. Here, by contrast, the errors were immaterial (*see infra* pages 21–23) and there are no particularized allegations suggesting that any Defendant was aware of the errors prior to February 2016 (*see infra* page 16–18).

[63] *See also Abiomed*, 778 F.3d at 242 ("If it is questionable whether a fact is material or its materiality is marginal, that tends to undercut the argument that defendants acted with the requisite intent or extreme recklessness in not disclosing the fact."); *Brennan* v. *Zafgen, Inc.*, 2016 WL 4203413, at *20 (D. Mass. Aug. 9, 2016) (holding that the marginal materiality of the information that was not disclosed weakens the inference that defendants either

plausible that Defendants would knowingly allow or conceal the premature recognition of such minimal revenue. *See In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d at 751 (affirming dismissal of securities fraud claims when the complaint included only "conclusory allegations that the defendant possessed 'contemporaneous' knowledge" that its statements were false or materially misleading when made).

Third, the Complaint is devoid of allegations that Defendants were aware of the revenue recognition errors before February 2016. The First Circuit has repeatedly stated that there is an "exacting standard" that must be satisfied with "clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so." *In re ARIAD Pharm., Inc.*, 842 F.3d at 751 (1st Cir. 2016). Plaintiffs do not dispute that Alere's senior management, including Individual Defendants, only learned of such potential issues in late February 2016.[64] Plaintiffs do not even allege that any employee at Alere's foreign subsidiaries misapplied GAAP or the Company's revenue recognition policy intentionally or discovered the revenue recognition errors before February 2016. *See Local No. 8 IBEW Ret. Plan & Trust*, 838 F.3d at 83 (affirming the dismissal of Section 10(b) claim and noting the lack of allegations "that anybody at [the company] responsible for receiving, reviewing, and reporting the results had actually spotted the error in the interpretation of the results before the discovery that led to the second [corrective] announcement"). Likewise, none of Plaintiffs' confidential witnesses claim that they themselves knew that revenue was being recognized prematurely under GAAP or the Company's internal

intentionally or recklessly misled investors); *Smith*, 55 F. Supp. 3d at 231 ("Large distortions in accounting figures caused by the alleged fraudulent actions support an inference of scienter." (internal citation omitted)).

64 Ex. 13, at 2.

policy or that any internal controls deficiencies concerning revenue recognition existed. *Id.*[65] Indeed, all of the confidential witnesses left the Company before the revenue recognition errors or the internal control deficiencies concerning revenue recognition were brought to senior management's attention (two left in 2014 and one in early 2015).[66] These allegations are insufficient to meet the exacting standards required in this Circuit.

Nor do Plaintiffs allege facts specific to any Individual Defendant regarding revenue recognition.[67] To the contrary, each Individual Defendant holds (or held, in the case of Ms. Flakne) the senior-most positions at Alere and had no reason to know the minutiae of any particular transaction or how transactions were accounted for by Alere's subsidiaries in China and Africa.[68] *See Cody* v. *Conformis, Inc.*, -- F. Supp. 3d --, 2016 WL 4132204, at *10 (D. Mass. Aug. 3, 2016) ("The Amended Complaint alleges no facts bearing on the mindset of the top executives of the company [and] . . . plaintiffs are left simply to speculate . . . . That guesswork does not measure up to the standard required by the PSLRA."); *In re Magnum Hunter Res. Corp. Sec. Litig.*, 26 F. Supp. 3d 278, 294–99 (S.D.N.Y. 2014) (citing authorities), *aff'd*, 616 Fed.

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[65] *See also In re Boston Sci. Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012) (noting that the First Circuit has found a strong inference of scienter in cases where "the complaint often contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so").

[66] *See Abiomed*, 778 F.3d at 245 (holding that the confidential witnesses not employed during the class period would not have "firsthand knowledge" of management's state of mind during that period); *Fitzer* v. *Sec. Dynamics Techs., Inc.*, 119 F. Supp. 2d 12, 39 (D. Mass. 2000) (rejecting allegations of former employees who "do not appear . . . to have been in a position to know the overall financial situation of the corporation" and cannot say "when management received or learned of" the undisclosed information); *Golesorkhi* v. *Green Mountain Coffee Roasters, Inc.*, No. 13-4048-cv, 2014 WL 2722753, at *1–2 (2d Cir. June 17, 2014) (affirming dismissal of Section 10(b) claim and noting that confidential witnesses' allegations "were not sufficiently close in time to the class period to support an inference of scienter").

[67] To the extent Plaintiffs intend to rely on the group-published information doctrine to plead scienter, they must still allege "sufficiently particularized allegations that the individual officer knew about the fraud." *In re Raytheon Sec. Litig.*, 157 F. Supp. 2d at 152.

[68] Furthermore, Mr. Hinrichs became Alere's CFO on April 6, 2015—after the revenue recognition errors had begun—a fact which further undermines any inference that he knew about the application of the GAAP rules to the particular contract terms or the errors. *See In re Segue Software*, 106 F. Supp. 2d at 169 n.17 (noting that plaintiffs' attribution of motive to individual defendants could not support scienter because the defendants were not employed by that company until later in relevant period).

App'x. 442, 445–46 (2d Cir. 2015) ("[P]laintiffs do not allege that defendants—notwithstanding their various statements regarding the company's internal controls and accounting errors—had the motive and opportunity to commit fraud sufficient to support scienter" (internal quotations omitted)). The confidential witnesses cannot fill this gaping hole because the Complaint does not allege that they either had any direct communication with any Individual Defendant or any reason to know what information the Individual Defendants received.[69] In fact, while the Individual Defendants worked in Massachusetts or California, at least two of the three confidential witnesses[70] worked in foreign subsidiaries. (The third confidential witness's place of employment is not identified.)

Fourth, Alere disclosed within days of discovering potential issues that it was delaying the filing of its 2015 Form 10-K to investigate the issues.[71] This prompt investigation and disclosure of the errors is completely inconsistent with an inference of scienter. *Messner* v. *USA Techs., Inc.*, No. 15-5427, 2016 WL 1466543, at *10 (E.D. Pa. Apr. 13, 2016) ("[T]he competing inference is more plausible: the financial persons responsible for accounting for these 'small-balance accounts', accounts which corporate executives most likely do not have particular knowledge of, mistakenly misclassified these 'bad debts'. When the Company realized the

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[69] *See N.J. Carpenters Pension & Annuity Funds* v. *Biogen IDEC Inc.*, 537 F.3d 35, 51 (1st Cir. 2008) ("[T]here must be a *hard look* at [confidential witness] allegations to evaluate their worth." (emphasis added)); *see also Abiomed*, 778 F.3d at 245 (holding that the confidential witnesses' statements do not "give rise to the requisite 'strong inference' of scienter on the part of [the Company] and its management" because none "were in senior management positions, and they appear to have had relatively little ongoing contact with senior management" (internal quotation marks omitted)); *In re Biogen Inc. Sec. Litig.*, No. 15-13189-FDS, 2016 WL 3541538, at *32–33 (D. Mass. June 23, 2016) (holding that the confidential witnesses' statements were not specific enough to support a strong inference because no witness was alleged to have spoken with any defendant); *Coyne* v. *Metabolix, Inc.*, 943 F. Supp. 2d 259, 267, 271 (D. Mass. 2013) (holding that a confidential witness's statements were "both conclusory and too vague" and lacked "specific facts capable of demonstrating that Defendants knew the information that [plaintiff] alleges contradicted their public statements").

[70] Both of these employees left Alere before Mr. Hinrichs joined; their statements are therefore entirely irrelevant to his state of mind.

[71] ¶ 79.

problem, it admitted its error, corrected its financial statements, and remediated the problem.").[72]

Fifth, any inference of fraud is further negated by the fact that Messrs. Nawana and Hinrichs *increased* their stock holdings and options during the putative class period.[73] (*See supra* pages 4–5.) Even more notably, Mr. Hinrichs used over a million dollars of his own cash to buy shares on the open market during the class period at prices between $39.97 and $49.88 per share.[74] These facts are flatly inconsistent with Plaintiffs' allegation that Defendants knew the stock price was artificially inflated. *See In re Bristol-Meyers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004) ("[T]he individual defendants, in almost every instance, increased their . . . holdings during the Class Period—a fact wholly inconsistent with fraudulent intent.").[75]

Sixth, Alere's disclosure of a material weakness in internal controls over financial reporting in connection with its disclosure of revenue recognition problems does not permit an inference that Defendants knew of the weakness earlier.[76] To the contrary, "[p]resumably every company that issues a financial restatement because of GAAP errors will cite as a reason lack of

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[72] *See In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 44 (1st Cir. 2014) (affirming dismissal and holding that the company's prompt investigation and disclosure of results "run[s] counter to any inference of scienter").

[73] *See In re Biogen*, 2016 WL 3541538, at *35 ("Indeed, the individual defendants' holdings of [the company's] stock actually *increased* during the class period according to the publicly-filed SEC Forms 4. That fact negates an inference that defendants had a motive to artificially inflate [the company's] stock price." (citing *Abiomed*, 778 F.3d at 246) (emphasis in original)); *N. Collier Fire Control*, 2016 WL 5794774, at *10 (noting that disposing shares to satisfy tax requirements on vested stock does not indicate fraudulent motive).

[74] Ex. 21, at 8, 10.

[75] Plaintiffs' suggestion that Messrs. Nawana and Hinrichs were motivated to recognize revenue prematurely because of their change-in-control benefits also fails to raise any inference of scienter. (¶¶ 2, 21, 27, 28.) Abbott first expressed its *unsolicited interest* in acquiring Alere on December 10, 2015—two and a half years after the revenue recognition errors commenced and several months before Alere's senior management became aware of them. Furthermore, the change-of-control payments to which they would be entitled are not tied to Alere's stock price nor are the amounts or terms alleged to be unusual. Notably, Ms. Flakne will not receive any payment if the merger with Abbott is consummated (*see* Ex. 17, at 27) and had announced her retirement mere days before Abbott expressed its interest in Alere (*see* Ex. 7, at 2). *See In re Vertex Sec. Litig.*, 357 F. Supp. 2d 343, 352–53 (D. Mass. 2005) (holding that a significant financial incentive, such as an upcoming merger, is insufficient alone to satisfy the scienter requirement).

[76] Notably, Alere's accountants never raised any concern regarding internal controls over revenue recognition in connection with the Company's prior financial statements. *Cf. Casula*, 2011 WL 4566115, at *7 (holding that outside auditor's approval of financial statements, even if the auditor did not specifically approve of the treatment of installation revenue, "weigh[s] heavily against an inference of" scienter).

effective controls." *Karpov* v. *Insight Enters., Inc.*, No. CV 09-856-PHX-SRB, 2010 WL 2105448, at *10 (D. Ariz. Apr. 30, 2010) (alteration in original) (internal citations omitted); *accord In re Turquoise Hill*, 2014 WL 7176187, at *8 (holding that the "accounting controls were an after-the-fact explanation for why the error had occurred, not a red flag before it was discovered"); *Roth* v. *OfficeMax, Inc*., 527 F. Supp. 2d 791, 797 (N.D. Ill. 2007).

Plaintiffs' emphasis on Alere's prior disclosures regarding *unrelated* material weaknesses also misses the mark. Plaintiffs assert that Alere's disclosures in March, May, and November 2015 of material weaknesses in internal controls relating to accounting for income taxes put the Individual Defendants on notice of entirely unrelated material weaknesses relating to revenue recognition practices in Africa and China.[77] But there is no similarity or relationship whatsoever between the income tax issues—which related to deferred taxes for discontinued operations and U.S. taxes on foreign earnings[78]—and the recognition of revenue for the particular transactions at issue here. Nor do Plaintiffs allege any such relationship other than in the most conclusory terms. *See Karpov*, 2010 WL 2105448, at *10 (holding that allegations of material weaknesses in internal controls "do not, standing alone, give rise to a strong inference of scienter" and plaintiffs must allege "specific details regarding how or under what circumstances [the] Defendants were aware of the weakness in internal controls or the connection between that weakness and trade credit accounting").[79]

Finally, Plaintiffs' allegations regarding certifications signed by Messrs. Nawana and Hinrichs under the Sarbanes Oxley Act ("SOX") are also insufficient to raise an inference of

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[77] *E.g.*, ¶¶ 3, 78–79, 96–97, 234.

[78] Ex. 6, at 6.

[79] *See also Ezra Charitable Trust*, 466 F.3d at 6 ("Pleading fraud by hindsight, essentially making general allegations that defendants knew earlier what later turned out badly, is not sufficient." (citation and internal quotation marks omitted)).

scienter. In the absence of particularized allegations that Messrs. Nawana and Hinrichs knew, or were highly reckless in failing to know, that revenue was being recognized early, the fact that they attested that "*based on their knowledge*" Alere's financial statements did not contain material misstatements and fairly presented the Company's financial condition is insufficient to raise an inference of scienter as a matter of law. *See In re Turquoise Hill*, 2014 WL 7176187, at *7 (holding that plaintiff's reliance on SOX certifications is "unavailing" because plaintiff "has not offered any particularized allegation of an inference that . . . the related CEO and CFO certifications pursuant to [SOX] were not honestly and reasonably believed to be true when made" (alterations in original accepted) (internal quotation marks omitted)).[80]

B. The Revisions to Alere's Financial Statements Were Immaterial as a Matter of Law.

Contrary to Plaintiffs' unsupported contention, the revisions here are immaterial in amount as a matter of law, as numerous courts in this district and elsewhere have repeatedly held at the motion to dismiss stage. *See, e.g.*, *Glassman* v. *Computervision Corp.*, 90 F.3d 617, 633 n.26 (1st Cir. 1996) (holding that a 9% discrepancy was insufficient to support a claim of materiality); *In re Segue Software*, 106 F. Supp. 2d at 170–71 (holding that a 2.6% overstatement of revenue was insignificant). As discussed above, Alere's net revenue and gross margin were revised by 0.5% or less for 2013, 2014, and the first 9 months of 2015. Such minor adjustments are deemed immaterial by both accountants and under the securities laws.[81] Indeed, consistent with the SEC's guidance in SAB No. 99, courts have held that financial errors resulting in a less

[80] *Accord Roth*, 527 F. Supp. 2d at 797; *see also Zucco Partners, LLC* v. *Digimarc Corp.*, 552 F.3d 981, 1004 (9th Cir. 2009) (noting that circuit courts that have ruled on this issue have "unanimously agreed that allowing [SOX] certifications to create an inference of scienter" would "eviscerate the pleading requirements for scienter set forth in the PSLRA" (alterations in original accepted) (citation and internal quotation marks omitted) (collecting cases)); *In re Ceridian Corp. Sec. Litig.*, 542 F.3d 240, 248 (8th Cir. 2008) (same).

[81] *See In re Segue Software*, 106 F. Supp. at 170.

than 5% impact are immaterial.[82] As a result, Alere determined that the revisions were immaterial to its previously issued financial statements—a conclusion that PwC agreed with and Plaintiffs do not challenge in the Complaint.[83]

Instead, Plaintiffs focus solely on the impact of the revisions on Alere's "Income (Loss) from Continuing Operations" for the first 9 months of 2015, which they repeatedly allege decreased by 67%.[84] Plaintiffs' emphasis on this 67% decrease is misleading in several respects and does not support their allegation of materiality. Most significantly, while Alere reported approximately $2.5 billion in net revenue and $1 billion in gross margin in each of 2014 and 2015, its Income (Loss) from Continuing Operations was a relatively small figure in the first 9 months of 2015—both before and after the revision: $18 million versus $6 million.[85] Thus, even a de minimis revision to Income (Loss) from Continuing Operations results in a large *percentage* change, rendering the difference to this line item a particularly meaningless way to evaluate materiality. Second, Plaintiffs' focus on just the first 9 months of 2015 is arbitrary and excludes

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[82] *See* SAB No. 99, 64 Fed. Reg. 45,150, 45,151 (Aug. 19, 1999); *accord United States* v. *Nacchio*, 519 F.3d 1140, 1162 (10th Cir. 2008), *vacated in part*, 555 F.3d 1234 (en banc) ("We take our cue from the SEC's guidelines for materiality of errors in reported revenues . . . that the misstatement or omission of an item that falls under a 5% threshold is not material in the absence of particularly egregious circumstances."); *ECA, Local IBEW Joint Pension Trust of Chi.* v. *JP Morgan Chase Co.*, 553 F.3d 187, 204 (2d Cir. 2009) (changing accounting treatment on 0.3% of total assets is quantitatively immaterial); *Dekalb Cty. Emps.' Ret. Sys.* v. *Controladora Vuela Compania De Aviacion, S.A.B. de C.V.*, No. 15CV1337, 2016 WL 3685089, at *4 (S.D.N.Y. July 6, 2016) (holding that a deferral representing "just 1.46% of fourth-quarter revenue and 0.36% of annual revenue" did "not even approach the numerical threshold (typically 5%) for quantitative materiality"); *see also Plumbers' Union Local No. 12 Pension Fund* v. *Nomura Asset Acceptance Corp.*, 658 F. Supp. 2d 299, 308–09 (D. Mass. 2009), *aff'd in part, vacated in part*, 632 F.3d 762 (1st Cir. 2011) (holding that no plausible question of materiality was raised when the loans at issue amounted to approximately 0.1% of the total pool of loans).

[83] Ex. 13, at 25, 32–33.

[84] *See, e.g.*, ¶¶ 6, 72, 104–105, 166.

[85] Alere consistently reports a relatively modest Income (Loss) from Continuing Operations because that figure nets out the amortization expenses on its acquired intangible assets and interest expense on its debt used to finance its acquisitions. When these non-cash items are taken into account, Alere's earnings are approximately $500 million (which is roughly the same as Alere's EBITDA during the same period). *See* Ex. 13, at 34 (listing $217 million in Interest Expenses, including amortization of original issues discounts and deferred financing costs), 35 (listing $309 million in Depreciation and Amortization); Ex. 14, at 10 (noting adjusted EBITDA was $499 million for fiscal year 2015).

much of the period when recognition errors occurred. When the revisions to Income (Loss) from Continuing Operations for the four quarters of 2014 are included, the difference drops to 5%.[86]

II. PLAINTIFFS FAIL TO PLEAD SECURITIES FRAUD REGARDING ALERE'S VOLUNTARY RECALL OF INRATIO PRODUCTS.

Plaintiffs contend that Alere failed to meet its reporting obligations under Accounting Standards Codification ("ASC") 450 two years before the INRatio product recall by failing, after it issued a voluntary correction notice in December 2014, either to accrue a loss contingency or to disclose the risk that such an accrual might ultimately be required.[87] Plaintiffs fail to allege any basis for this contention or that Defendants knew—or could have known—before July 2016 that a loss contingency would be necessary, and therefore, fail to state a securities fraud claim. *Cody*, 2016 WL 4132204, at *10 (rejecting "speculat[ion] as to what [defendants] might have known or thought").

ASC 450 requires accrual of a loss contingency when it is both probable that a liability has been incurred and the amount can be reasonably estimated.[88] Alternatively, ASC 450 requires disclosure of a loss contingency when the loss is reasonably possible (i.e., "the likelihood that it will occur is more than remote but less than likely") but cannot be estimated.[89]

As Plaintiffs' allegations reflect, beginning as early as May 2014, Alere proactively disclosed problems with its INRatio products to investors, the FDA, and INRatio users.[90] Alere expressly disclosed in connection with its May 2014 recall and December 2014 correction that it was investigating the INRatio issues. In December 2014, Alere also stated that it was working on

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86 Ex. 13, at 25–27.

87 ¶¶ 183–191.

88 ¶ 183.

89 *In re Lions Gate Entm't Corp. Sec. Litig.*, 165 F. Supp. 3d 1, 21 (S.D.N.Y. 2016); *see also* ¶ 183.

90 ¶¶ 52, 188.

an improvement for the devices[91] and disclosed in its 2014 Annual Report on Form 10-K:

> We have encountered product issues related to our Alere INRatio systems resulting in a May 2014 recall of our Alere INRatio2 PT/INR Professional Test Strips in the United States and a December 2014 voluntary urgent medical device correction initiated with respect to our Alere INRatio and Alere INRatio2 systems to inform users not to use these systems to test patients with certain medical conditions. We have transitioned customers from the recalled Alere INRatio2 PT/INR Professional Test Strip to the Alere INRatio PT/INR Test Strip, which was not included in the recall. While it is too early to understand the full impact of the voluntary urgent medical device correction, we believe that our emphasis on quality during 2014 has enabled us to respond to these developments more effectively than in the past and will help to mitigate any negative impact. We plan to continue our improvements to quality and regulatory compliance during 2015 and beyond.[92]

After discovering issues with the INRatio devices, Alere invested in further research during 2015 to develop software enhancements, which it submitted to the FDA at the end of that year.[93] At the same time, Alere specifically disclosed the risk that its INRatio products could be subject to recall:

> Our business is subject to substantial regulatory oversight and our failure to comply with applicable regulations may result in significant costs or, in certain circumstances, the suspension or withdrawal of previously obtained clearances or approvals. . . .
>
> The FDA and foreign regulatory agencies may require post-market testing and surveillance to monitor the performance of approved products or may place conditions on any product approvals that could restrict the commercial applications of those products. The discovery of problems with a product may result in restrictions on the product, including notices of correction or product recalls, such as our December 2014 voluntary urgent medical device correction initiated with respect to our Alere INRatio and Alere INRatio2 systems and our April 2014 recall of our Alere INRatio2 PT/INR Professional Test Strips, or even withdrawal of the product from the market.[94]

Thus, the market was fully and candidly apprised of the status of the INRatio products and the

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91 ¶ 187; Ex. 4, at 2.

92 Ex. 5, at 15.

93 ¶ 187.

94 Ex. 5, at 9 (emphasis omitted).

attendant risks. *Ezra Charitable Trust* v. *Tyco Int'l, Ltd.*, 466 F.3d 1, 8 (1st Cir. 2006) (affirming dismissal of securities fraud claims for lack of scienter where company's Form 10-K contained cautionary notes, such as "We cannot predict when these investigations will be completed, nor can we predict what the results of these investigations may be").

Without mentioning any of these disclosures, Plaintiffs rely on (i) the eventual occurrence of a voluntary recall in July 2016 and (ii) the December 2014 voluntary correction informing patients that they should not use the INRatio products if they have certain medical conditions.[95] Neither of these facts establishes that a loss contingency was either probable or reasonably possible under ASC 450. *See Zaluski* v. *United Am. Healthcare Corp.*, 527 F.3d 564, 577 (6th Cir. 2008) (affirming dismissal on the grounds that plaintiff failed to plead with particularity facts alleging that a loss was sufficiently probable or possible to require a loss accrual or contingency disclosure).

Defendants were under no obligation to assume that the steps Alere was taking to rectify the issues would be unsuccessful; indeed, only a limited group of users were affected by the December 2014 correction. Further, the FDA only recommended that Alere expand its recall after reviewing the software enhancements that Alere submitted at the end of 2015 and deciding it was not satisfied that they were effective.[96] *See, e.g.*, *In re Boston Tech., Inc. Sec. Litig.*, 8 F. Supp. 2d 43, 58 (D. Mass. 1998) (dismissing Section 10(b) claim because it "rests on an assumption that defendants must have known of the severity of their [product-related] problems earlier because conditions became so bad later on" and such "fraud by hindsight is insufficient

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[95] ¶¶ 187–188. In particular, the December 2014 voluntary correction notified only users with certain medical conditions not to use the INRatio devices, including severe infections, chronic or acute inflammatory conditions, advanced stage cancer, or any bleeding or unusual bruising. Ex. 4, at 1.

[96] *See* FDA Firm-Initiated Recall Rule, 21 C.F.R. § 7.46 (providing the FDA with authority to "recommend any appropriate changes in the firm's strategy for the recall" where a firm has initiated a voluntary recall); *see also* FDA, *Regulatory Procedures Manual* Ch. 7, at 5 & 15-16 (Oct. 2013), *available at* http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074312.pdf (last visited Feb. 5, 2017).

under Rule 9(b)").[97] Nor were Defendants obligated to remove the INRatio line of products from the market until they better understood the issues and their origin. *See In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 42 (2d Cir. 2000) ("[T]he early medical reports may have indicated a potential problem, but until a connection . . . could be made, we would not expect [defendant] to abandon its product on what, at the time, would have been speculation.").[98]

The First Circuit reaffirmed these principles in its recent decision *Ganem* v. *Invivo Therapeutics Holdings Corp.*, in which it reiterated that "'fraud by hindsight' does not satisfy the pleading requirements in a securities fraud case." --- F.3d ---, 2017 WL 74702, at *7 (1st Cir. January 9, 2017). The plaintiff in *Ganem* claimed that a company's disclosures regarding the timing of a study and submission of the study data to the FDA were misleading because it failed to disclose certain FDA conditions that "inevitably prevented" the company from achieving the timeline. *Id.* at *6–7. Noting the lack of any allegations to support his claim, the court said that the plaintiff was instead "left only with the inference that because, in retrospect, the test lagged significantly behind the proposed timeline, the timeline must have always been impossible to achieve." *Id.* at *7. In dismissing the claim, the First Circuit explained that the "securities laws do not make it unlawful for a company to publicize an aggressive timeline or estimate for a proposed action without disclosing every conceivable stumbling block for realizing those plans." *Id.*

Moreover, whether or to what extent it is appropriate to establish a loss reserve is quintessentially a matter of *judgment*—an opinion that Plaintiffs must allege was not honestly

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[97] *See also ACA Fin. Guar. Corp.*, 512 F.3d at 62 ("A plaintiff may not plead 'fraud by hindsight'; i.e., a complaint may not simply contrast a defendant's past optimism with less favorable actual results in support of a claim of securities fraud" (internal quotation marks omitted)); *Ezra Charitable Trust*, 466 F.3d at 6 (same); *Fitzer*, 119 F. Supp. 2d at 20 (same).

[98] *See also Slayton* v. *Am. Exp. Co.*, 604 F.3d 758, 777 (2d Cir. 2010) (disclosure delay did not support securities fraud claim where defendants conducted good-faith investigation).

held. Plaintiffs' allegations do not support an inference that Defendants' judgment that a loss contingency was not reasonably possible before July 2016 was not held in good-faith. *Fait* v. *Regions Fin. Corp.*, 655 F.3d 105, 113 (2d Cir. 2011) ("[D]etermining the adequacy of loan loss reserves is not a matter of objective fact. Instead, loan loss reserves reflect management's opinion or judgment about what, if any, portion of amounts due on the loans ultimately might not be collectible."); *In re Hutchinson Tech. Inc. Sec. Litig.*, 502 F. Supp. 2d 884, 895 (D. Minn. 2007), *aff'd*, 536 F.3d 952 (8th Cir. 2008) ("Of course, the mere fact that returns exceeded return allowances would provide little, if any, evidence that the return allowances were knowingly false. After all, return allowances are estimates, and even the most honest and careful estimate will often turn out to be wrong.").[99]

The confidential witnesses' statements also do not support any inference that Alere lacked a good-faith basis for its judgment or that Defendants acted with scienter. The confidential witnesses (the "Global VP of Customer Service" and a "Quality Assurance [] Product Support Associate") do not state that they are accountants, that they were involved in any discussions regarding the accounting here, or that they know about the Defendants' state of mind as to the accounting judgment. Indeed, neither one claims to have had any contact with the Individual Defendants. Neither confidential witness was in a position to assess whether a product recall was appropriate or necessary, as both were allegedly involved in resolving customer complaints. *See Biogen IDEC Inc.*, 537 F.3d at 51 (stating the need for a "*hard look*" at confidential witness allegations to evaluate their worth (emphasis added)). And, the customer

[99] *Accord N. Collier Fire Control*, 2016 WL 5794774, at *10 (dismissing plaintiffs' claim that defendant failed to record the appropriate impairment to goodwill as "nothing more than disagreement with [defendant]'s accounting judgments, which cannot support a fraud claim"); *see also In re Segue Software*, 106 F. Supp. 2d at 170 ("Accounting judgments, even imperfect ones that violate GAAP, do not, absent 'other circumstances,' support an inference of scienter."); *Casula* v. *athenahealth, Inc.*, No. 10-10477-GAO, 2011 WL 4566115, at *7 (D. Mass. Sept. 30, 2011) (noting that an "honest mistake of judgment" does not support an inference of scienter); *supra* note 62 (discussing *Raytheon Sec. Litig.*, 157 F. Supp. 2d 131).

complaints they discuss are not inconsistent with the disclosures Alere made throughout the period. Even accepting their statements as accurate, they do not even claim that the July 2016 recall was inevitable or should have occurred earlier.[100] *In re Biogen Inc. Sec. Litig.*, No. 15-13189-FDS, 2016 WL 3541538, at *34 (D. Mass. June 23, 2016) (holding that "absent more particularized details and stripped of their generalities, the confidential witness allegations . . . are not clearly inconsistent with what defendants were publicly disclosing to the market").

Plaintiffs have failed to allege any basis to infer that Defendants' judgment that, prior to July 2016, ASC 450 did not require either a disclosure or an accrual with respect to this loss contingency was not honestly held. Plaintiffs' sole basis for their argument is that because Alere commenced an investigation into the INRatio products, it must have known earlier what the eventual result with FDA would be.[101] *See In re Apollo Grp., Inc. Sec. Litig.*, No. CV-10-1735-PHX-JAT, 2011 WL 5101787, at *16 (D. Ariz. Oct. 27, 2011) (holding that plaintiffs' allegations that defendants violated ASC 450 by failing to establish adequate allowances for certain receivables did not support a strong inference of scienter because plaintiffs only provide "conclusory assertions that defendants knew" they would not be able to collect these amounts).[102]

Even assuming Plaintiffs were correct that Alere should have disclosed the reasonable possibility of a loss under ASC 450 sooner, the securities fraud claim still fails because Plaintiffs

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[100] *See* ¶¶ 48–50. It is not clear from the Complaint whether the first confidential witness was even employed by Alere after 2007. Further, while vague, the second confidential witness's statement that "Alere needed to recall the INRatio device because 'it didn't work'" appears to be about the May 2014 recall and could not have involved the July 2016 recall, which occurred nearly half a year after she left Alere. *See* ¶ 49.

[101] *See* ¶¶ 187–191.

[102] *Int'l Ass'n of Heat* v. *Int'l Bus. Machines Corp.*, -- F. Supp. 3d. --, 2016 WL 4688862, at *7 (S.D.N.Y. Sept. 7, 2016) (dismissing Section 10(b) claim because the allegations failed to raise a strong inference that the need to impair an asset "was so apparent" to the Defendants that "a failure to take an earlier write-down amounts to fraud"); *Fait*, 655 F.3d at 113 ("[I]n order for the alleged statements regarding the adequacy of loan loss reserves to give rise to liability under sections 11 and 12, plaintiff must allege that defendant's opinions were both false and not honestly believed when they were made."); *Ezra Charitable Trust*, 466 F.3d at 6 (rejecting a pleading of "fraud by hindsight").

have not alleged that Alere intentionally violated this accounting rule. *Smith* v. *First Marblehead Corp.*, 55 F. Supp. 3d 223, 231 (D. Mass. 2014) ("Allegations of GAAP violations or accounting irregularities, standing alone, are insufficient to state a securities fraud claim." (internal quotation marks omitted)) (quoting *Day* v. *Staples, Inc.*, 555 F.3d 42, 45 (1st Cir. 2009)). In fact, there are no allegations about who made the decision, what was discussed, or that any Individual Defendant had information contrary to the disclosures made. The lack of scienter is especially evident in light of the following: (i) Alere actually disclosed the relevant facts and risks to investors (as described above);[103] (ii) ASC 450 is a highly technical accounting rule for which there is very little published guidance; and (iii) the recall of the INRatio products was immaterial to Alere's overall financial performance because less than 2% of Alere's net revenue in 2015 was generated from the INRatio products and the charge (most of which was for non-cash items) that Alere took in 2015 in connection with the recall was only $38 million.

Plaintiffs also contend that Alere should have disclosed that "facts existed raising the likelihood of an investigation of Alere by the DOJ relating to the accuracy, reliability and performance of the INRatio products."[104] Contrary to Plaintiffs' allegations, Alere had no duty to predict (nor could it) that the DOJ would commence an investigation into the INRatio products. *Cf. In re Boston Sci. Corp. Sec. Litig.*, 490 F. Supp. 2d 142, 154 (D. Mass. 2007) (holding that the company "was not obligated to predict the outcome or estimate the impact of the litigation").[105] After receiving the DOJ's subpoena in May 2016, the Company satisfied its

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[103] *Ezra Charitable Trust*, 466 F.3d at 8 ("[A]ttempts to provide investors with warnings of risks generally weaken the inference of scienter.").

[104] *See* ¶ 225.

[105] *Richman* v. *Goldman Sachs Grp., Inc.*, 868 F. Supp. 2d 261, 274 (S.D.N.Y. 2012) ("Defendants were not obligated to predict and/or disclose their predictions regarding the likelihood of suit."); *see also City of Brockton Ret. Sys.* v. *Avon Prods., Inc.*, 2014 WL 4832321, at *29 (S.D.N.Y. Sept. 29, 2014) ("[B]y announcing that an internal FCPA investigation had been undertaken, and that the SEC and DOJ had been advised of that

obligations by disclosing it shortly thereafter in its 2015 Form 10-K.[106] *See City of Pontiac Policemen's & Firemen's Ret. Sys.* v. *UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014) ("By disclosing its involvement in multiple legal proceedings and government investigations and indicating that its involvement could expose UBS to substantial monetary damages and legal defense costs, as well as injunctive relief, criminal and civil penalties[,] and the potential for regulatory restrictions, UBS complied with its disclosure obligations under our case law." (internal quotation marks omitted) (alterations in original)).

III. PLAINTIFFS FAIL TO PLEAD SECURITIES FRAUD REGARDING BILLING PRACTICES WITHIN ALERE'S TOXICOLOGY UNIT.

Plaintiffs' claims relating to Alere's toxicology unit are premised on conclusory allegations that Alere failed to disclose (i) "billing improprieties . . . ongoing at [its] toxicology unit for years" and (ii) "illegal kickbacks."[107] But Plaintiffs fail to allege a single fact to support the conclusion that any billing improprieties or illegal kickbacks actually occurred or that any Individual Defendant knew of improprieties committed at Alere's toxicology unit.

To support their theory of wrongdoing, Plaintiffs focus on the DOJ subpoena received in July 2016[108] seeking Medicare, Medicaid, and Tricare billing records from Alere's Austin, Texas laboratory (which accounted for "significantly less than 1% of Alere's total revenues" in the first 9 months of 2015).[109] But the mere pendency of a regulatory investigation is insufficient to support allegations of wrongdoing. *See Menaldi* v. *Och-Ziff Capital Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 578 (S.D.N.Y. 2016), *reconsideration denied*, No. 14-CV-3251 (JPO), 2016 WL

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investigation, Avon put the investing public on notice that Avon might be exposed to criminal and regulatory investigations, significant damage to reputation, and other losses and costs." (internal quotation marks omitted)).

[106] Ex. 13, at 20.

[107] ¶¶ 215–216.

[108] Ms. Flakne had already retired from Alere at this point.

[109] Ex. 10, at 1; ¶ 236.

2642223 (S.D.N.Y. May 6, 2016) ("When a securities fraud action rests on the failure to disclose uncharged illegal conduct, the complaint must state a plausible claim that the underlying conduct occurred."); *Brophy* v. *Jiangbo Pharm.*, 781 F.3d 1296, 1303–04 (11th Cir. 2015) (finding that the mere existence of a government investigation "does not equip a reviewing court to explain which inferences might be available beyond a general suspicion of wrongdoing"); *see also Loos* v. *Immersion Corp.*, 762 F.3d 880, 890 (9th Cir. 2014) ("The announcement of an investigation does not 'reveal' fraudulent practices to the market. Indeed, at the moment an investigation is announced, the market cannot possibly know what the investigation will ultimately reveal."). Further, Alere's prompt disclosure of this subpoena satisfied its obligations under the federal securities laws. *See UBS AG*, 752 F.3d at 184.

Nor do the confidential witnesses on whom Plaintiffs rely support allegations that the misconduct occurred or that the Individual Defendants knew about it. Neither confidential witness held a senior position within Alere nor is alleged to have communicated with any Individual Defendant. The first left Alere almost three years before the start of the putative class period and before Messrs. Nawana and Hinrichs joined Alere, and before Ms. Flakne was Chief Accounting Officer. This confidential witness states that Alere conducted unnecessary additional tests in connection with toxicology screenings that resulted in a number of clients discontinuing their use of Alere for drug testing.[110] These allegations have nothing to do with the Austin pain management laboratory, and the Complaint does not allege that they do. The second confidential witness appears to have been at Alere for less than six months—also before the class period began and before Messrs. Nawana and Hinrichs joined Alere. She reports nothing other than her purported discovery that, during two Medicare audits and an internal audit, certain documents

[110] ¶ 62.

had not been appropriately maintained.[111] But these audits have nothing to do with billing improprieties, kickbacks, or fraud of any sort. *Cf. In re Boston Sci. Corp. Sec. Litig.*, 10 Civ. 10593 (DPW), 2011 WL 4381889, at *15 (D. Mass. Sept. 19, 2011) (explaining that an internal audit "does not show corporate negligence, but rather suggests corporate responsibility").

Finally, Plaintiffs rely on (i) a complaint Horizon Blue Cross and Blue Shield filed in 2013 "alleging that [Alere] committed insurance fraud" (the "Horizon Complaint")[112] and (ii) the departure of "a number of high-level executives in Alere's toxicology business."[113] These allegations do not support a claim that the misconduct at issue here occurred or the requisite strong inference of Defendants' scienter. Regarding the Horizon Complaint, "allegations from other complaints or documents, which are unproved and are contested, may not be used to establish facts to demonstrate scienter." *ScripsAmerica, Inc.* v. *Ironridge Global LLC*, 119 F. Supp. 3d 1213, 1262–63 (C.D. Cal. 2015) (collecting cases). And, in any event, as Plaintiffs concede, the litigation involved Avee Laboratories, Inc.—a Florida laboratory acquired by Alere in October 2011.[114] Similarly, the timing of the resignations of the toxicology unit executives does not permit a strong inference of fraud. Plaintiffs have not alleged that any of these executives engaged in *any* misconduct. *See, e.g.*, *Washtenaw Cnty Emps. Ret. Sys.* v. *Avid Tech., Inc.*, 28 F. Supp. 3d 93, 113 (D. Mass. 2014) (noting that "[i]n reality, there are any number of

[111] ¶ 64. It is worth noting that such audits are routinely conducted in the ordinary course of Alere's business and Alere disclosed this fact along with the associated risks to its business: "Governmental payers and their agents . . . conduct audits in the ordinary course of our operations. These audits focus on compliance with coverage and reimbursement rules and guidelines under Medicare and Medicaid. These types of audits often lead to determinations that certain claims should not have been paid by Medicare and/or Medicaid, and the programs seek to recoup or offset amounts they assert have been paid in error. We regularly receive notices of such determinations of overpayment, which vary widely in amount. These determinations are subject to administrative appeal rights, which we routinely pursue. . . . Depending on the nature of the audit, overpayment determinations can be substantial." Ex. 5, at 10–11; *see also* Ex. 13, at 17–18, 20.

[112] ¶ 61.

[113] ¶ 63.

[114] *See* ¶ 61; Ex. 1, at 8.

reasons that an executive might resign, most of which are not related to fraud").[115]

Given Plaintiffs' fundamental failure to plead that any wrongdoing actually occurred or any fact raising a strong inference of scienter, their securities fraud claim regarding Alere's toxicology unit should be dismissed.

IV. PLAINTIFFS FAIL TO PLEAD SECURITIES FRAUD REGARDING ALERE'S COMPLIANCE WITH THE FCPA.

As with the toxicology unit claim, Plaintiffs' claim regarding Alere's compliance with the FCPA suffers from a fundamental defect that compels its dismissal: The mere fact that Alere received a subpoena from the DOJ regarding FCPA compliance does not suggest that the any wrongdoing actually occurred or that Defendants had any knowledge of any wrongdoing.[116] As such, it fails to establish that either Alere in fact violated the FCPA[117] or that Defendants knew of any such alleged improprieties.

Plaintiffs' remaining allegations regarding Defendants' knowledge of Alere's purported FCPA violations are attributable to a confidential witness, an alleged former National Sales Manager in India from 2013 through early 2015. That witness claims that (i) Alere's audit firm conducted an investigation into government bidding practices in India, (ii) "Alere's policies for ensuring adherence to anti-corruption laws were not open or transparent [and] most of Alere's practices in India did not match global policies," and (iii) Alere's distributors and state

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[115] *Accord Vertex Pharm.*, 838 F.3d at 85 (holding that because the complaint failed to allege that a retired executive knew something that other defendants did not, it would be inconsistent with the PLSRA to infer that her retirement was due to unlawful conduct as opposed to other reasons).

[116] *See, e.g.*, *Washtenaw Cnty Emps. Ret. Sys.*, 28 F. Supp. 3d at 114 (stating that a government investigation "is insufficient in and of itself" to support an inference of scienter); *City of Austin Police Ret. Sys.* v. *ITT Educ. Servs., Inc.*, 388 F. Supp. 2d 932, 949 (S.D. Ind. 2005) (noting that a company's receipt of a subpoena "falls well short of notice of wrongdoing"); *Cortina* v. *Anavex Life Sci. Corp.*, No. 15-CV-10162, 2016 WL 7480415, at *8 (S.D.N.Y. Dec. 29, 2016) (two government investigations did not give rise to a compelling inference of scienter in the absence of allegations of motive); *accord In re Manulife Fin. Corp. Sec. Litig.*, 276 F.R.D. 87, 102 (S.D.N.Y. 2011) ("Securities regulators are obligated to examine the behavior of public corporations, and the fact that a regulator is fulfilling this role cannot be sufficient to allege scienter.").

[117] *See Menaldi*, 164 F. Supp. 3d at 578.

government officials engaged in "under the table" dealings.[118] These vague allegations do not suffice to indicate that Defendants were aware that Alere engaged in unlawful conduct.[119] Significantly, the confidential witness does not state that the audit firm's investigation uncovered any wrongdoing. Nor does he allege any knowledge on the part of any Individual Defendant. Plaintiffs do not allege that the confidential witness ever communicated with any Individual Defendant or has any reason to know what any Individual Defendant knew about the matters alleged. Without more, this confidential witness's statements fail to raise any inference of scienter, let alone the strong inference required by the PSLRA.[120]

V. PLAINTIFFS FAIL TO PLEAD SECURITIES FRAUD REGARDING THE REVOCATION OF ARRIVA'S ELIGIBILITY TO BILL MEDICARE.

Plaintiffs claim that Alere failed to disclose that facts existed "that would give rise" to the revocation of Arriva's eligibility to submit claims to Medicare by CMS.[121] In particular, Plaintiffs contend that Alere had a duty to disclose (i) that, according to the government, Arriva "submitted at least 211 claims to CMS on behalf of deceased patients" over a multi-year period,[122] and (ii) that, in August 2015, CMS restricted Arriva's access to the HETS system, thereby impairing Arriva's ability to guard against submitting claims on behalf of deceased patients.[123]

Although the Complaint makes the conclusory allegation that "Defendants knew or recklessly disregarded" that Arriva had submitted claims on behalf of deceased patients to

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118 ¶¶ 66–67.

119 *See supra* note 69; *see also In re Huntington Bancshares Inc. Sec. Litig.*, 674 F. Supp. 2d 951, 960 (S.D. Ohio 2009) (noting that "the who, what, when, where, and how a confidential witness knew of information should be definite, as allegations that are too vague and conclusory are not to be accorded much weight").

120 *In re Biogen*, 2016 WL 3541538, at *35; *see also supra* note 69.

121 ¶ 5.

122 ¶ 203.

123 ¶ 205.

CMS,[124] it is devoid of ***any*** particularized allegations that Defendants were aware of any such claims before October 2016, when CMS first notified Arriva of the submission of invalid claims. Notably, Alere disclosed that it received a letter from CMS two weeks after receiving it.[125] The Complaint does not even allege that any employee of Alere's Arriva subsidiary was aware before October 2016 that invalid claims had been submitted.[126] Nor does the Complaint allege that with respect to any of the 211 claims, Arriva did not in fact ship products to the patients in the good faith belief that they were still alive.

Conspicuously, there are no statements from any confidential witness that ascribes knowledge of allegedly invalid claims to any Defendant or Arriva employee or otherwise supports this fraud claim. Nor does CMS's October 2016 letter allege either that Arriva had intentionally submitted claims on behalf of deceased beneficiaries or that Arriva (let alone Alere) was aware of such submissions.[127]

It is undisputed that the 211 claims allegedly submitted on behalf of deceased beneficiaries represent less than 0.003% of the 5.7 million claims Arriva submitted during the five-year period identified in CMS's letter, and that Arriva did not retain payment for any of those claims. The more compelling inference is that Alere senior management would not have known of such minor errors in the process in which a subsidiary submitted claims.[128] Nor are there any plausible allegations that Alere acted with fraudulent intent. It would be completely irrational for a company to jeopardize its eligibility to bill Medicare, and millions of dollars in annual revenue, by intentionally filing a miniscule number of improper claims over five years.

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[124] ¶ 203.

[125] ¶ 133.

[126] *See Vertex Pharm.*, 838 F.3d at 83.

[127] Nor does the CMS letter suggest that there is any health risk or concern that prompted its revocation of Arriva's eligibility to submit claims to Medicare.

[128] *See Cody*, 2016 WL 4132204, at *10.

The more compelling inference to draw from the facts alleged in the Complaint is that the submission of any claims on behalf of deceased beneficiaries were unintentional errors by the Arriva subsidiary and that Defendants knew nothing about it. *See Tellabs*, 551 U.S. at 328–29.

Plaintiffs' contention that Alere had a duty to disclose that, beginning in August 2015, CMS limited Arriva's access to the HETS system is also baseless. The Complaint does not allege that Arriva lacked its own robust internal controls for safeguarding against submission of invalid claims to CMS. Nor does the Complaint allege that there were any deficiencies or flaws in Arriva's internal controls or that any concerns on that subject were ever raised with Alere's senior management. Moreover, the Complaint does not allege that the independent vendor that Arriva hired to regularly monitor and audit a sample of its patients' orders ever identified any invalid claims.[129] Indeed, the Complaint does not even allege that the Individual Defendants were aware of the changes that CMS had made to Arriva's access to HETS in 2015. There is thus no basis for inferring that the 2015 limits would have placed Alere senior management on notice that there was now a significantly greater risk that Arriva would submit claims to CMS on behalf of deceased patients.[130]

Plaintiffs also assert that Defendants were "on notice of significant compliance issues at Arriva since, at the latest, March 5, 2015,"[131] based solely on Alere's disclosure on that date that Arriva was responding to a Civil Investigative Demand ("CID") relating to an investigation into the submission "of possible improper claims." The mere pendency of this investigation does

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[129] Ex. 19, at 1.

[130] *See In re Comshare Inc. Sec. Litig.*, 183 F.3d 542, 554 (6th Cir. 1999) (holding that "the Complaint fails to allege facts that give rise to a strong inference of scienter" because plaintiff failed to plead facts that show revenue recognition errors at a subsidiary should have been obvious to the parent company).

[131] ¶ 138.

not serve as notice that claims were being submitted on behalf of deceased beneficiaries.[132] Indeed, Plaintiffs do not allege that the investigation either concerns claims submitted for deceased beneficiaries or deficiencies in Arriva's internal controls relating to submissions of claims to CMS.

Finally, Plaintiffs' assertion that Arriva "had a long, recidivist history" fails to raise any inference of scienter. This allegation is based on one *qui tam* action filed in 2009 against another company AmMed Direct LLC ("AmMed"), three years ***before*** Arriva even acquired the assets of AmMed.[133] As Plaintiffs concede, the *qui tam* action involved wholly unrelated violations of Medicare rules (*i.e.*, improper marketing and retention of funds for returned products) that occurred years before Arriva acquired AmMed.[134] This entirely unrelated matter arising out of conduct predating Arriva's involvement cannot support any inference of scienter.

VI. PLAINTIFFS FAIL TO PLEAD SECURITIES FRAUD REGARDING THE MERGER AGREEMENT.

First, Plaintiffs' allegations that the Merger Agreement between Abbott and Alere contains false and misleading statements and omissions are premised on the same misconceived theories about Alere's revenue recognition, existing regulatory investigations, and the revocation of Arriva's eligibility to bill Medicare and fail for all the same reasons addressed above.[135]

Second, Plaintiffs' suggestion that Defendants were concealing Alere's revenue recognition errors in order to attract a merger offer is illogical. Abbott's *unsolicited* offer to acquire Alere was made in December 2015—just days before the end of the fiscal year in which the last of any of the revenue recognition errors occurred and two short months before Alere's

[132] Nor does the pendency of an investigation "reveal" any other fraudulent practices to the market. *See Loos*, 762 F.3d at 890.

[133] ¶¶ 135–136.

[134] ¶ 136.

[135] ¶¶ 222, 223; *see also* ¶¶ 76–77.

senior management learned of (and promptly disclosed) the errors.

Third, neither of the two lawsuits between the merger partners in the Delaware Chancery Court discloses any new or actionable information. The details of Alere's dispute with Abbott over the Merger Agreement, including the parties' dispute over access to information and documents, have been disclosed in near real-time for months.[136] Plaintiffs concede that, even prior to the filing of the MAE action, Abbott had "publicly expressed doubt at proceeding with the Merger."[137] Indeed, a prior complaint that Plaintiffs filed in this action on September 23, 2016 is replete with allegations that Abbott might seek to terminate the Merger.[138] Similarly, as early as April 2016, several analyst reports cited in the Complaint discuss termination of the Merger Agreement as a distinct possibility. Ex. 9, at 1 ("If [Abbott] no longer feels ALR [is] the 'perfect fit' for its business, it could press the Dept of Justice investigation and 10-K delay in a Material Adverse Event clause argument in court."); Ex. 8, at 1 ("We now peg a . . . 25% probability on the deal falling apart.").

Thus, Abbott's lawsuits were simply the materialization of the risks of which the market was already aware. *See In re Boston Sci. Corp.*, 490 F. Supp. 2d at 154 ("As the Second Circuit has noted, loss resulting from the materialization of a disclosed risk does not support a claim of securities fraud."), *rev'd and remanded on other grounds sub nom.*, *Mississippi Pub. Emps' Ret. Sys.* v. *Boston Sci. Corp.*, 523 F.3d 75 (1st Cir. 2008).

Finally, Plaintiffs attempt to bolster their scienter allegations by quoting unproven allegations Abbott made in its opposition to Alere's Motion for Expedited Proceedings and its

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[136] *See, e.g.*, Ex. 18, at 3; Ex. 20, at 1.

[137] ¶ 8.

[138] *See* ECF. No. 64, ¶¶ 7, 78, 82.

complaint in the MAE Action.[139] However, unproved allegations drawn from lawyers' advocacy in unrelated legal proceedings cannot support an inference of scienter. *See Aronson* v. *Advanced Cell Tech., Inc.*, 972 F. Supp. 2d 123, 136 (D. Mass. 2013) (granting motion to dismiss, in part, and observing that "[a] pleading may not adopt other pleadings from a wholly separate action"). Furthermore, even if Abbott were to prevail in its efforts to terminate the Merger Agreement, that outcome would not support Plaintiffs' securities claims in this action. Abbott does need to plead (and does not attempt to plead) that Defendants acted with scienter. Rather, Abbott's lawsuit turns on whether the events enumerated amount to a material adverse effect and entitle Abbott to terminate the Merger Agreement. Thus, the pendency of the MAE action does not demonstrate the adequacy of Plaintiffs' pleadings in this action.

CONCLUSION[140]

For the reasons set forth above, Defendants respectfully request that the Court dismiss the Complaint with prejudice.[141]

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[139] ¶¶ 241–243.

[140] Given Plaintiffs' failure to state a primary violation of the Exchange Act by any Defendant, the Section 20(a) claim asserted against the Individual Defendants also fails. *See Vertex Pharm.*, 838 F.3d at 86.

[141] *Abiomed, Inc.*, 778 F.3d at 247 (noting that the First Circuit "discourage[s] th[e] practice of seeking leave to amend after the case has been dismissed"); *ACA Fin. Guar. Corp.*, 512 F.3d at 57–58 (affirming denial of motion for leave to amend and rejecting plaintiffs' "wait and see" strategy).

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, filed through the CM/ECF System, will be served electronically on the registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent to those indicated as nonregistered participants via first class mail this 6th day of February 2017.

/s/ *Richard A. Rosen*